IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

KELLY DIODATO,	*	
Plaintiff,	*	
v.	*	
		CIVIL NO. JKB-20-762
MENTOR WORLDWIDE LLC.,	*	
Defendant.	*	

* * * * * * * * * * * *

MEMORANDUM

Plaintiff Kelly Diodato sued Defendant Mentor Worldwide LLC ("Mentor"), claiming that a defective silicone gel breast implant manufactured by Mentor injured her. Mentor moved to dismiss (ECF No. 12) on the grounds that Plaintiff's claims are preempted. The motion is fully briefed and no hearing is required. *See* Local Rule 105.6 (D. Md. 2018). For the reasons set forth below, the Court will dismiss Plaintiff's claims without prejudice.

I. Background

Mentor manufacturers the MemoryGel Silicone Gel Breast Implant ("MemoryGel Implant"). (Mot. Dismiss Mem. at 3–4, ECF No. 12-1.) The MemoryGel Implant is a "Class III" medical device regulated by the U.S. Food and Drug Administration ("FDA"). (PMA Approval Order, Mot. Dismiss Ex. A, ECF No. 12-2.)[1] In April of 2014, Dr. Lawrence Rosenberg performed a breast augmentation surgery on Plaintiff during which two MemoryGel Implants were implanted. (Compl. ¶ 2, ECF No. 3.) Subsequently, Plaintiff "developed a persistent lump in the middle of

[1] The Court takes judicial notice of the information contained in this document and the other publicly available FDA documents submitted as exhibits to Mentor's motion. *See United States v. Garcia*, 855 F.3d 615, 621 (4th Cir. 2017) (noting courts "routinely take judicial notice of information contained on state and federal government websites").

her chest" and began to experience "alopecia, and poor circulation in her fingertips." (*Id.* ¶¶ 6–7.) In February of 2019, Dr. Sarah Mess "diagnosed Plaintiff's symptoms as being caused by a leaking implant," and in April of 2019, Plaintiff had both implants removed. (*Id.* ¶ 9.) Dr. Mess "documented an intracapsular implant rupture of the left implant." (*Id.* ¶ 10.)

Plaintiff alleges that this rupture was "a condition which was created by [Mentor] and which existed since the time the implant left [Mentor's] possession." (*Id.* ¶ 4.) Plaintiff alleges that "Dr. Rosenberg implanted [Mentor's] aforementioned product into Plaintiff's body without inspecting the implant or detecting a hole[.]" (*Id*. ¶ 3.) Plaintiff also alleges that Mentor negligently "failed to advise physicians and end users of risk of such a hole existing." (*Id.* ¶ 13.) The Complaint does not disclose the foundation for Plaintiff's belief that the rupture existed at the time the implant left Mentor's possession. Likewise, the Complaint includes no discussion of Mentor's manufacturing process or of any warnings Mentor provides.

On January 17, 2020, Plaintiff filed suit against Mentor and Johnson & Johnson Services, Inc. in the Circuit Court for Baltimore County, Maryland. (Compl.) Plaintiff brought three counts against each Defendant: (1) Negligence; (2) Strict Liability; and (3) Breach of Warranty. The gravamen of Plaintiff's case is that Mentor defectively manufactured her implant, then warranted its safety and failed to provide a warning that it might be defective. The Defendants removed the matter to this Court (Not. Removal, ECF No. 1), then moved to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) (ECF No. 12). After filing her opposition (ECF No. 15), Plaintiff voluntarily dismissed her claims against Johnson & Johnson Services, Inc. (ECF Nos. 18, 20), leaving Mentor the sole Defendant. The primary issue in dispute is whether Plaintiff's common law claims are preempted by federal law.

II. Legal Standards

"In considering a motion to dismiss" pursuant to Rule 12(b)(6), the Court must "accept as true all well-pleaded allegations and view the complaint in the light most favorable to the plaintiff." *Venkatraman v. REI Sys., Inc*., 417 F.3d 418, 420 (4th Cir. 2005). To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*.

III. Analysis

Mentor argues that Plaintiff's claims are subject to preemption under the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360 *et seq.*, to the federal Food Drug and Cosmetic Act ("FDCA"). The Court agrees. Though it is possible that Plaintiff may be able to state a claim against Mentor that is not subject to preemption, the Complaint fails to do so.

The MDA grants the FDA regulatory authority over medical devices and imposes a "regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The statute divides medical devices into three categories, with Class III medical devices receiving the most intense scrutiny. *Id*. at 316–17. Class III medical devices must undergo a "rigorous process" of "premarket approval" before the FDA will allow such devices to be sold. *Id.* at 317. "To obtain pre-market approval, a device manufacturer must submit to the FDA" a detailed application including, among many other components, "a full description of the manufacturing methods and the facilities and controls used for the device's manufacturing." *Walker v. Medtronic, Inc*., 670 F.3d 569, 572–73 (4th Cir. 2012) (citing 21 U.S.C. § 360e(c)(1)). Where, as here, the FDA grants

premarket approval, the approval requires the device to be manufactured "with almost no deviations from the specifications in its approval application." *Riegel*, 552 U.S. at 323.

In *Riegel v. Medtronic, Inc.*, the Supreme Court held that the MDA expressly preempts state common law claims that would impose "state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law.'" 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)(1)). In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court additionally held that implied preemption prevents a plaintiff from suing a defendant merely for failing to satisfy its obligations to the FDA. 531 U.S. 341 (2001). Therefore, a plaintiff's state law claim relating to a Class III medical device is preempted unless the claim is "premised on conduct that both (1) violates the MDA and (2) would give rise to a recovery under state law even in the absence of the MDA." *Winkler v. Medtronic, Inc*., Civ. No. PX-18-00865, 2018 WL 6271055, at *4 (D. Md. Nov. 29, 2018) ("*Winkler I*") (quoting *Williams v. Smith & Nephew, Inc*., 123 F. Supp. 3d 733, 746 (D. Md. 2015)). If a complaint fails to allege conduct satisfying both of these prongs, it must be dismissed. *See In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig*., 623 F.3d 1200, 1204 (8th Cir. 2010) (explaining the MDA creates "a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption") (quoting *Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

Here, each of Plaintiff's claims falls before the preemption bar, because the Complaint does not include any allegation that Mentor's conduct violated the MDA. Starting with Plaintiff's manufacturing defect claims, Plaintiff claims that Mentor is subject to both strict liability and liability for negligence in relation to the alleged hole in Plaintiff's left implant. The Complaint alleges that a hole existed at the time the implant left Mentor's possession, and reasons that the alleged existence of such a hole necessarily implies a manufacturing defect. However, in a case

involving a Class III medical device, it is not enough that the plaintiff allege the existence of a deficiency. In addition, the plaintiff must allege "how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process." *Funk v. Stryker Corp*., 631 F.3d 777, 782 (5th Cir. 2011); *see also*, *Ebrahimi v. Mentor Worldwide LLC*, 804 F. App'x 871, 872 (9th Cir. 2020) ("[M]ere allegations suggesting that [plaintiff's] particular breast implants were defective do not show that Mentor failed to comply with the FDA's Current Good Manufacturing Practices.") (internal quotations and citations omitted). The Fourth Circuit and courts in this District have repeatedly dismissed claims challenging allegedly defective Class III medical devices where the plaintiff fails to allege a particular deviation from the FDA approved manufacturing process and relies on the alleged fact of the defect alone. *See, e.g., Walker,* 670 F.3d at 580–81 ("[C]ommon law tort claims based on the failure of devices that were designed, manufactured, and sold in accordance with the terms of their premarket approval [are] preempted[.]"); *Winkler v. Medtronic, Inc*., Civ. No. PX-18-00865, 2019 WL 6052702, at *3 (D. Md. Nov. 15, 2019) ("*Winkler II*") (granting dismissal because plaintiffs alleged "standard, garden variety, common law negligence claims, and provide[d] no specificity as to the manner in which Defendants violated [applicable] FDA regulations"); *Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div*., Civ. No. CCB-12-1746, 2013 WL 1104427, at *4 (D. Md. Mar. 13, 2013) (granting dismissal because plaintiffs "allege[d] no deviation from the prescribed PMA manufacturing process").

Here, Plaintiff has not alleged any deviation from the manufacturing process approved by the FDA. Indeed, Plaintiff has provided no information at all regarding this manufacturing process and no theory regarding how the alleged rupture occurred. As such, the manufacturing defect claims must be dismissed.

The same goes for Plaintiff's failure to warn and warranty claims. Plaintiff alleges that Mentor inaccurately warranted that its MemoryGel Implant was fit for use and that Mentor negligently failed to warn Dr. Rosenberg and Plaintiff of the dangers associated with MemoryGel Implants. However, Plaintiff again fails to allege any divergence between Mentor's conduct and the requirements imposed by the FDA. What is more, Plaintiff entirely fails to address the fact that the publicly available, FDA-approved MemoryGel Breast Implants Product Insert Data Sheet specifically warns of the possibility of rupture and notifies physicians that they should carefully inspect a MemoryGel Implant before implantation. (Product Insert Data Sheet, Mot. Dismiss. Ex. D, ECF No. 12-5.) As such, the conclusory assertions of wrongdoing in the Complaint are subject to dismissal. *C.f. Winkler II*, 2019 WL 6052702, at *3 (dismissing failure to warn and warranty claims because plaintiffs "averred no facts by which this Court could plausibly infer any violations of the FDA requirements").

Dismissal will be granted without prejudice. Though Plaintiff has failed to state a claim, the Court is not convinced that any amendment is certain to be futile. *See Ostrzenski v. Seigel,* 177 F.3d 245, 252–53 (4th Cir. 1999) ("A dismissal under Rule 12(b)(6) generally is not final or on the merits[,]" and dismissal should be granted with leave to amend unless "it appears to a certainty that plaintiff cannot state a claim.") (quoting 5A C. Wright & A. Miller, Federal Practice and Procedure § 1357 (2d ed.1990)). Since it remains possible that Plaintiff could allege tortious conduct which also violated federal law, dismissal with prejudice is unwarranted.

IV. Conclusion

For the foregoing reasons, an order shall enter dismissing the Complaint without prejudice.

DATED this 19th day of June, 2020.

BY THE COURT:

/s/

James K. Bredar
Chief Judge